UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,353	11/14/2003	Janine Schuurman	GMI-059	6363

959 7590 05/02/2006

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER	
BRISTOL, LYNN ANNE	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/714,353	SCHUURMAN ET AL.	
	Examiner	Art Unit	
	Lynn Bristol	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-98 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-98 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The specification and Sequence Listing do not appear to provide sequence identifiers for the amino acid sequences in Claims 40, 43, 46 and 49. Pursuant to 37 CFR 1.821, a sequence identifier must be provided for any amino acid sequences of four or more residues or nucleotide sequences of 10 or more nucleotides. Accordingly, since the specification, Sequence Listing and Claims 40, 43, 46 and 49 and the dependent claims thereof are not in sequence compliance, claims 40-50 are withdrawn from restriction. Applicants will need to provide a revised Sequence Listing, a computer readable form of the Sequence Listing and a statement. Please see the attached Notice to Comply Form, for which the Examiner has set the time limit as set in this action for the response.

2. Claim 98 is drawn to a "use" of an anti-idiotypic antibody, which recites non-statutory subject matter under U.S. practice. The claim has been interpreted as a method of detection for purposes of this restriction.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   1. Claims 7, 20 and 21, drawn to antibodies encoded by polynucleotides encoding for a CD 25 binding antibody, the variable regions of human heavy (SEQ ID NO: 5) and human light (SEQ ID NO: 7) chains from the AB7 Mab and modifications thereof, classified in class 536, subclass 23.53.

2. Claim 8, drawn to antibodies encoded by polynucleotides encoding for a CD 25 binding antibody, the variable regions of human heavy (SEQ ID NO: 13) and human light (SEQ ID NO: 15) chains from the AB12 Mab and modifications thereof, classified in class 536, subclass 23.53.
3. Claim 9, drawn to antibodies encoded by polynucleotides encoding for a CD 25 binding antibody, the variable regions of human heavy (SEQ ID NO: 1) and human light (SEQ ID NO: 3) chains from the AB1 Mab and modifications thereof, classified in class 536, subclass 23.53.
4. Claim 10, drawn to antibodies encoded by polynucleotides encoding for a CD 25 binding antibody, the variable regions of human heavy (SEQ ID NO: 9) and human light (SEQ ID NO: 11) chains from the AB11 Mab and modifications thereof, classified in class 536, subclass 23.53.
5. Claims 11 and 12, drawn to a CD 25 binding antibody comprising the amino acid sequences of the variable regions of human heavy (SEQ ID NO: 6) and human light (SEQ ID NO: 8) chains from the AB7 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.
6. Claims 13 and 14, drawn to a CD 25 binding antibody comprising the amino acid sequences of the variable regions of human heavy (SEQ ID NO: 14) and human light (SEQ ID NO: 16) chains from the AB12 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.
7. Claims 15 and 16, drawn to a CD 25 binding antibody comprising the amino acid sequences of the variable regions of human heavy (SEQ ID

NO: 2) and human light (SEQ ID NO: 4) chains from the AB1 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

8. Claims 17 and 18, drawn to a CD 25 binding antibody comprising the amino acid sequences of the variable regions of human heavy (SEQ ID NO: 10) and human light (SEQ ID NO: 12) chains from the AB11 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

9. Claim 19, drawn to a CD 25 binding antibody comprising the amino acid sequences of the variable regions of human heavy (SEQ ID NOS: 2, 6, 10 or 14) and human light (SEQ ID NOS: 4, 8, 12 or 14) chains from the AB1, AB7, Ab11 and AB12 Mabs, respectively, and homologous sequences thereof, classified in class 424, subclass 133.1 or 144.1.

10. Claims 22-27, drawn to a CD 25 binding Mab comprising amino acid sequences from the heavy (SEQ ID NOS:23-25) and light chain (SEQ ID NOS: 26-28) CDRs of the AB7 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

11. Claims 28-31, drawn to a CD 25 binding Mab comprising amino acid sequences from the heavy (SEQ ID NOS:29-31) and light chain (SEQ ID NOS: 32-34) CDRs of the AB11 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

12. Claims 32-35, drawn to a CD 25 binding Mab comprising amino acid sequences from the heavy (SEQ ID NOS:35-37) and light chain (SEQ ID

NOS: 38-40) CDRs of the AB12 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

13. Claims 36-39, drawn to a CD 25 binding Mab comprising amino acid sequences from the heavy (SEQ ID NOS:17-19) and light chain (SEQ ID NOS: 20-22) CDRs of the AB1 Mab and modifications thereof, classified in class 424, subclass 133.1 or 144.1.

14. Claim 51, drawn to a CD 25 binding antibody comprising a VH amino acid sequence derived from human Vh1-69/JH4b or Vh1-69/JH5b germline sequence and a VL amino acid sequence derived from human A27/Jk4 or A27/Jk5 germline sequence, classified in class 424, subclass 133.1 or 144.1.

15. Claim 52, drawn to a CD 25 binding antibody comprising a VH amino acid sequence derived from human Vh1-69/D7-27/JH4b or Vh1-69/D7-27/JH5b germline sequence and a VL amino acid sequence derived from human A27/Jk4 or A27/Jk5 germline sequence, classified in class 424, subclass 133.1 or 144.1.

16. Claim 56, drawn to a CD25 binding and IL-2 binding inhibiting fusion protein, classified in class 424, subclass 133.1.

17. Claim 63 in part, drawn to a transgenic animal comprising polynucleotides encoding the human HC and LC for a CD 25 binding antibody, classified in class 800, subclass 13.

18. Claim 63 in part, drawn to a transgenic plant comprising polynucleotides encoding the human HC and LC for a CD 25 binding antibody, classified in class 800, subclass 295.

19. Claim 64, drawn to methods for producing human anti-CD25 Mab using a transgenic nonhuman animal, classified in class 424, subclass 132.1 or class 800, subclass 6 or class 435, subclass 449.

20. Claim 67, drawn to a CD25 binding antibody comprising a chelator linker for a radioisotope, classified in class 424, subclass 179.1.

21. Claim 68, drawn to an immunoconjugate comprising a CD 25 binding antibody, classified in class 424, subclass 181.1.

22. Claim 69, drawn to a bispecific or mutlispecific antibody comprising a CD 25 binding antibody, classified in class 424, subclass 136.1.

23. Claims 70, 72, 83-87, drawn to methods for inhibiting CD25-expressing cell growth or proliferation with a CD 25 binding antibody, classified in class 424, subclass 156.1.

24. Claim 71, drawn to methods of killing CD 25 expressing cells with a CD 25 binding antibody, classified in class 424, subclass 156.1.

25. Claim 73 in part, 74, 75 and 77-82, drawn to methods for treating disorders involving CD 25 expressing cells using a CD 25 binding antibody, classified in class 424, subclass 156.1.

26. Claim 73 in part, and 74-82, drawn to methods for preventing disorders involving CD 25 expressing cells using a CD 25 binding antibody, classified in class 424, subclass 144.1.

27. Claim 88, drawn to methods for detecting CD 25 expression using a CD 25 binding antibody, classified in class 424, subclass 144.1.

28. Claims 90-95, drawn to expression vectors encoding VL, VH, CH, and CV domains and modifications thereof from a CD 25 binding antibody, and pharmaceutical compositions thereof, classified in class 435, subclass 320.1.

29. Claims 96 and 97, drawn to anti-idiotypic antibodies binding to a CD 25 binding antibody, classified in class 424, subclass 131.1.

30. Claim 98, drawn to methods of detecting the level of a human anti-CD 25 Mab, classified in class 435, subclass 7.1.

4. Claims 1-6, 53-55, 57, 57-62, 65, 66 and 89 links inventions for Groups 1-30. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1-6, 53-55, 57, 57-62, 65, 66 and 89. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims is/are presented in a continuation or divisional

application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP § 804.01.

5. The antibodies encoded by polynucleotides of Groups 1-4, the antibodies of amino acid sequences of Groups 5-16, 20-22 and 29, and the expression vectors of Group 28 are related. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function or effect. See MPEP § 806.05(j). In the instant case, the antibodies of Groups 1-4 do not overlap the scope of the antibodies for Groups 5-16, 20-22 and 29, and the expression vectors of Group 28 do not overlap the scope of any of the antibodies of Groups 1-16, 20-22 and 29 as evidence by the distinct structures and functions of the claimed inventions. A DNA's structure is comprised of linear, contiguous nucleotides, an expression vector is comprised of contiguous nucleotides encoding regulatory elements with DNA insertions operatively linked and encoding regions and domains for a protein while a protein's structure is comprised of linear, contiguous amino acids that fold into a specific three-dimensional structure; the DNA's function is to encode a protein, the expression vector's function is to express a protein encoded by the DNA while a protein's function, in the instant case, is to bind human CD 25. Additionally, the DNA, expression vectors and

polypeptides are not obvious variants of each other based on the distinct structures and functions of each as noted above. Lastly, the DNA, expression vectors and polypeptides have materially different functions as noted above.

With respect to the antibodies of Groups 1-4, each represents an antibody having a unique polynucleotide or DNA sequence with domains or regions for each sequence being derived from a different Mab (AB1, Ab7, Ab11, AB12).

With respect to each of the antibodies of Groups 5-16, 20-22 and 29, each represents an antibody having a unique amino sequence with each sequence being translated from a unique mRNA. The antibodies can also comprise different domains selected from the AB1, AB7, Ab11 or Ab12 Mabs and used in various combinations. Also, the antibodies of Groups 20-22 can also comprise additional linking groups or conjugation forms, which further modifies their structures and/or binding properties.

Because these inventions are distinct for the reasons given above and the search required for Groups 1-4 and 28 is not required for Groups 5-16, 20-22 and 29, restriction for examination purposes as indicated is proper. While the Groups can be identically classified under U.S. Patent Classification guidelines, to search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Groups 5-16, 20-22 and 29, drawn to polypeptides, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the DNA

sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups 1-16, 20-22, 28 and 29 have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

6. Inventions Groups 17 and 18 (transgenic animals and plants) and Groups 1-16, 20-22 and 29 (polypeptides) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed in the specification as capable of use together. Additionally, the construction and design of a transgenic animal or plant is different from the polypeptides for antibodies. To obtain recombinant antibodies from any one of the transgenic sources for Groups 17 and 18 would require also require using different vector expression constructs depending on whether the antibody was expressed transiently or stably, or whether the antibody is expressed by an animal cell or whole animal or a plant cell or a whole plant. The antibody could also differ in post-translational modifications of the protein, again, depending on the transgenic source from which it was derived. Finally, extracting the antibody from each of the sources would require different steps. The transgenic animals or plants would operate or function to produce recombinant antibodies in vivo whereas the polypeptide antibodies would function by binding to a specific antigen in vitro or in vivo. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues.

7. The methods of Groups 19, 23-27 and 30 differ in the method objectives, method steps, intended populations, and in the reagents used. The methods of Groups 19, 23-27 and 30 differ as follows: Group 19 requires that a nonhuman animal possess a human heavy chain and human light chain transgene, and immunizing the animal with human CD 25 or a cell expressing human CD25 to produce and isolate anti-CD25 antibody expressing B cells for fusion with a myeloma cell in order to produce anti-CD 25 antibodies in culture; Group 23 requires administering a cell growth or cell proliferation inhibiting amount of a CD 25 binding antibody to cells expressing CD 25 in order to inhibit growth or proliferation; Group 24 requires administering a cell killing amount of a CD 25 binding antibody to cells expressing CD 25 in order to eliminate the cells; Group 25 requires administering a therapeutically effective amount of a CD 25 binding antibody in treating a disorder involving CD 25 expressing cells; Group 26 requires administering a prophylactically effective amount of a CD 25 binding antibody in preventing a disorder involving CD 25 expressing cells; Group 27 requires contacting a sample with a CD 25 binding antibody in order to detect the presence of CD 25 antigen or a cell expressing CD 25; and Group 30 requires contacting a sample with an anti-idiotypic antibody for an anti-CD 25 antibody in order to detect the level of anti-CD 25 antibody. The transgenic pigs would operate or function to produce recombinant antibodies in vivo whereas the polypeptide antibodies would function by binding to a specific antigen in vitro or in vivo. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus methods of Groups 19, 23-27 and

30 are separate and distinct in having different method steps, different endpoints and different reagents used, and thus are patentably distinct.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper. To search Groups 1-30 together would also present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive. Thus, Groups 1-30 have been appropriately restricted on the basis of being both distinct and presenting a search burden on the Examiner if they were to be searched together.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Election of Species Requirement

11. If Group 21 is elected, then species (immunoconjugate) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) cytotoxic agent

Specie B) radioisotope

Specie C) drug

The drug molecule species A-C do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any reference manual (e.g., Merck Index, Physician's Desk Reference, the Red Book, Goodman & Gillman) or the U.S. Pharmacopeia (USP.org) describing the structure, solubility characteristics, biological properties and/or contraindications for each of the species, and would appreciate that based on these reference disclosures alone or in combination, that these species are distinct and separate. The species are not obvious variants or overlapping, thus to search the species together would present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 68 is generic as to Species A-C.

12. If Group 22 is elected, then species (binding specificity for bispecific or multivalent antibody) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) CD3

Specie B) CD4

Specie C) IL-15R

Specie D) membrane bound or receptor bound TNF-α

Specie E) membrane bound or receptor bound IL-15

Species A-E are CD antigens, each well recognized in the art as being expressed on different cell types, having different structural proteins, different cognate ligands and signal interactions. For example, any commercial Table of CD antigens lists this information. In addition, The Human Protein Reference Database (HPRD.org) describes the tissue expression patterns, structural and functional properties and any disease correlates for the receptors of species A-E. The species are not obvious variants or overlapping, thus to search the species together would present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 69 is generic as to Species A-E.

13. If Group 23 is elected, then species (immunosuppressant therapeutic agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) cyclosporine

Specie B) azathioprine

Specie C) mycophenolic acid

Specie D) mycophenolate mofetil

Specie E) prednisone

Specie F) methotrexate

Specie G) gold salts

Specie H) sulfasalazine

Specie I) antimalarials

Specie J) brequinar

Specie K) leflunomide

Specie L) mizoribine

Specie M) 15-deoxyspergualine

Specie N) 6-mercaptopurine

Specie O) cyclophosphamide

Specie P) rapamycin

Specie Q) tacrolimus (FK-506)

Specie R) OKT3

Specie S) anti-thymocyte globulin

See the comments under section 11, supra, as they apply to these species of molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 70 is generic as to Species A-S.

14. If Group 23 is elected, then species (anti-inflammatory therapeutic agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) steroidal drug

Specie B) NSAID (nonsteroidal anti-inflammatory drug),

Specie C) DMARD (methotrexate, hydroxychloroquine, sulfasalazine, leflunomide)

Specie D) IL-1 receptor blocking agents (anakinara)

Specie E) TNF-α blocking agents (etanercept, infliximab, adalimumab)

Specie F) anti-IL-6R antibodies

Specie G) CTLA4Ig

Specie H) anti-IL-I5 antibodies

See the comments under section 11, supra, as they apply to these species of molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 70 is generic as to Species A-H.

15. If Group 23 is elected, then species (anti-inflammatory or hyperproliferative skin disorder therapy) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) coal tar

Specie B) A vitamin

Specie C) anthralin

Specie D) calcipotrien

Specie E) tarazotene

Specie F) corticosteroids

Specie G) methotrexate

Specie H) cyclosporine

Specie I) etanercept

Specie J) alefacept

Specie K) efaluzimab

Specie L) 6-thioguanine

Specie M) mycophenolate mofetil

Specie N) tacrolimus (FK-506)

Specie O) hydroxyurea

Specie P) phototherapy (UVB (broad-band and narrow-band ultraviolet B), UVA (ultraviolet A) and PUVA (psoralen methoxalen plus ultraviolet A)

See the comments under section 11, supra, as they apply to these species of molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 70 is generic as to Species A-P.

16. If Group 23 is elected, then species (therapeutic agent) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) doxorubicin

Specie B) cisplatin

Specie C) bleomycin

Specie D) carmustine

Specie E) chlorambucil

Specie F) cyclophosphnmide

See the comments under section 11, supra, as they apply to these species of molecules.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 70 is generic as to Species A-F.

17. If Group 25 or 26 is elected, then species (disorder involving CD25 expressing cells) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) transplant rejection

Specie B) graft-versus-host disease

Specie C) immune, autoimmune or inflammatory disease

Specie D) inflammatory or hyperproliferative skin disorder

Specie E) lymphoid neoplasm

The species A-E do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the immune disorders: has a different etiology; involves a different arm of the immune response (e.g., humoral and/or cellular); has a different clinical course and outcome(s) that are influenced by endogenous autocrine and paracrine effects of cytokines, growth factors, hormones, etc.; and each disorder is recognized as being managed by different therapeutic approaches. One could consult any medical textbook to appreciate the different evaluation, clinical work-up and recommended clinical management for each of these separate and distinct disorders. The species are not obvious variants or overlapping, thus to search the species together would present a search burden on the Examiner due to the extensive databases of non-patent literature and because searching the databases is not co-extensive.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-E.

18. If transplant rejection of Group 25 or 26 is elected, then nested species below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) allograft transplant rejection

Specie B) xenograft rejection

See the comments under section 17, supra, as they apply to these disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A and B.

19. If graft-versus-host disease of Group 25 or 26 is elected, then nested species below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) blood transfusion graft-versus-host disease

Specie B) bone marrow graft-versus-host disease.

See the comments under section 17, supra, as they apply to these disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A and B.

20. If immune, autoimmune or inflammatory disease of Group 25 or 26 is elected, then nested species below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) rheumatoid arthritis

Specie B) ankylosing spondylitis

Specie C) psoriatic arthritis

Specie D) type 1 diabetes

Specie E) insulin-requiring type 2 diabetes

Specie F) multiple sclerosis

Specie G) systemic lupus erythematosus

Specie H) myasthenia gravis

Specie I) inflammatory bowel disease

Specie J) Crohn's disease

Specie K) ulcerative colitis

Specie L) dermato-polymyositis

Specie M) Sjögren's syndrome

Specie N) arteritides

Specie O) giant cell arteritis

Specie P) aplastic anemia

Specie Q) asthma

Specie R) scleroderma

Specie S) uveitis

See the comments under section 17, supra, as they apply to these disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-S.

21. If inflammatory or hyperproliferative skin disorder of Group 25 or 26 is elected, then nested species below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) plaque psoriasis

Specie B) pustulosis palmoplantaris (PPP)

Specie C) erosive lichen planus

Specie D) pemphigus bullosa

Specie E) epidemolysis bullosa

Specie F) contact dermatitis

Specie G) atopic dermatitis

See the comments under section 17, supra, as they apply to these disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-G.

22. If lymphoid neoplasm of Group 25 or 26 is elected, then nested species below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) T cell leukemia

Specie B) Hodgkin's disease

Specie C) hairy cell leukemia

Specie D) mycosis fungoides

Specie E) Sezary's syndrome

The species A-E do not share a common utility nor do they have a substantial structural feature common amongst them. Each of the cancers of species A-E can originate from any number of different cell types (e.g., epithelial, endothelial or mesothelial). Also, the cancers being associated with different organs are nevertheless, under the influence of different growth factors and hormones. Additionally, numerous studies have shown that receptor density and affinity for different therapeutic biomolecules is highly variable amongst different tissues and organs, in addition to there being differences to the extent to which biomolecules are able to penetrate cancers. Thus, species A-E are patentably distinct cancers. Additionally, searching all of the species would be burdensome for the examiner because the searches would not be co-extensive as a result of each of the cancers having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-E.

23. If Group 25 or 26 is elected, then species (malignancy) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) gastric cancer

Specie B) esophageal cancers

Specie C) malignant melanoma

Specie D) colorectal cancer

Specie E) pancreas cancer

Specie F) breast cancer

Specie G) small cell lung cancer

Specie H) non-small cell lung cancer

Specie I) cervical cancer

Specie J) ovarian cancer

Specie K) renal cell carcinoma

See the comments under section 22, supra, as they apply to these species of cancer.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-K.

24. If Group 25 or 26 is elected, then species (hematological disease) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) adult T cell leukemia/lymphoma

Specie B) anaplastic large cell lymphoma

Specie C) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)

Specie D) peripheral T cell lymphoma

Specie E) secondary amyloidosis

See the comments under section 17, supra, as they apply to these disorders.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 73 is generic as to Species A-E.

25. If Group 29 is elected, then species (idiotype binding target) below must be elected as applicable. This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A) AB1

Specie B) AB7

Specie C) AB11

Specie D) AB12

The species of monoclonal antibody A-D are each distinct. Although the monoclonals are all anti-CD 25 antibodies, these antibodies are considered to be unrelated, since each of the antibodies is structurally and functionally independent and distinct for the following reasons: each antibody has a unique amino acid sequence, each antibody binds to a different epitope and each antibody has its own unique ability to stimulate an immune response and/or binding affinity to an antigen or epitope. Additionally, searching all of the species would be burdensome because the searches would not be co-extensive as a result of each of the monoclonals having obtained a separate status in the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 97 is generic as to Species A-D.

26. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LAB

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER

Notice to Comply	Application No. 10/714,353	Applicant(s) SCHUURMAN ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

The specification and Sequence Listing do not appear to provide sequence identifiers for the amino acid sequences in Claims 40, 43, 46 and 49. Pursuant to 37 CFR 1.821, a sequence identifier must be provided for any amino acid sequences of four or more residues or nucleotide sequences of 10 or more nucleotides.